K011255

DEC 2 0 2001

510(k) Summary

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

1. The submitter of this premarket notification is:

Karen H. Rigamonti, M.D., M.B.A.
President
3D line USA, Inc.
2807 Old Court Road
Baltimore, Md. 21208

This summary was prepared on April 19, 2001.

2. The name of the device is the 3D Line Stereotactic Hardware Accessories and it is used with a linear accelerator (LINAC) to immobilize the patient's head and allow the LINAC to be aimed at a brain tumor and other types of lesions and to immobilize the patient while the treatment is taking place. This application does not include the LINAC. Common names for this device are Stereotaxy Instruments and LINAC-based Stereotactic Radiotherapy System Accessories

3. The above device is substantially equivalent to the Radionics XKnife® Accessories that were developed from the Radionics CRW® Stereotactic System.

4. The above device includes four (4) sub-assemblies: the Stereotactic Invasive Head Frame (using screws that slightly penetrate the patient's skull) for single treatments, the Stereotactic (non-invasive) Relocatable Frame for multiple treatments, the Stereotactic Collimator to control the size of the LINAC's beam and the Stereotactic Couch Stand to secure one of the Head Frames to the LINAC's couch. The device includes components that allow it to be used with magnetic resonance imaging (MR), computerized tomography (CT), and angiography and to be aligned with the laser beam on the LINAC.

5. The technological characteristics of the device are the same or similar to those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen H. Rigamonti, M.D., M.B.A.
President
3D Line USA, Inc.
2807 Old Court Road
Baltimore, Maryland 21208

DEC 2 0 2001

Re: K011255
Trade/Device Name: 3D Line Sterotactic Hardware Accessories
Regulation Number: 892.5050, 882.4560
Regulation Name: Medical charged-particle radiation therapy system
Stereotaxic instrument
Regulatory Class: II
Product Code: IYE, HAW
Dated: September 22, 2001
Received: September 25, 2001

Dear Ms. Rigamonti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011255

Device Name: Stereotactic Hardware Accessories

Indications for Use:

This device is intended to hold a patient's head in a fixed position and to localize and center the output of a linear accelerator (LINAC) to allow radiotherapy of brain tumors and other types of cerebral lesions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011255